

REMARKS

Claims 1-9 are pending in this application. The Office Action rejects claims 1-9 under 35 U.S.C. §112, first paragraph; and rejects claims 1-9 under 35 U.S.C. §103(a). By this Amendment, claims 1-9 are amended. Support for this amendment may be found in the present specification at, for example, paragraphs [0056] and [0060]. No new matter is added.

Entry of the amendments is proper under 37 CFR §1.116 because the amendments: (a) place the application in condition for allowance (for the reasons discussed herein); (b) do not raise any new issue requiring further search and/or consideration (as the amendments amplify issues previously discussed throughout prosecution); and (c) place the application in better form for appeal, should an appeal be necessary. The amendments are necessary and were not earlier presented because they are made in response to arguments raised in the final rejection. Entry of the amendments is thus respectfully requested.

I. Rejection under 35 U.S.C. §112, first paragraph

Claims 1-9 are rejected under 35 U.S.C. §112, first paragraph, for allegedly failing to comply with the written description requirement.

Without admitting the propriety of the rejection, and in the interest of advancing prosecution, claims 1-9 are amended. Specifically, the claims are amended to recite "a method of treating MELAS." Applicant respectfully asserts that the fully scope of the amended claims is supported by the specification, for example at paragraphs [0056] and [0060].

Reconsideration and withdrawal of the rejection are respectfully requested.

II. Rejection under 35 U.S.C. §103(a)

Claims 1-9 are rejected under 35 U.S.C. §103(a) as having been obvious over Fukumi (JP 2003-335664). Applicant respectfully traverses this rejection.

Applicant respectfully asserts that Fukumi does not teach or suggest all the features of amended independent claim 1. Specifically, Fukumi at least fails to teach or suggest a method of treating MELAS. See the present specification at, for example, paragraphs [0021], [0056] and [0060]. Instead, Fukumi merely lists a variety of other disorders, which the composition taught therein might treat, but does not disclose and offers no reason or rationale for treating MELAS specifically. Specifically, Fukumi merely discloses treating "presenium encephalopathy (senile dementia and an Alzheimer disease)" and "myoclonus syndrome." Fukumi at paragraph [0010].

As is known to a person having ordinary skill in the art, MELAS is a distinctly different disease than presenium encephalopathy or myoclonus syndrome. As is generally known, the term "encephalopathy" merely refers to any injury or disorder of the brain. The term "presenium" is generally known to mean relating to the period preceding old age. Therefore, the treatment of presenium encephalopathy disclosed by Fukumi relates to entirely different disorders than the *mitochondrial* encephalopathy of MELAS. The mere fact that both disorders are *types of* encephalopathy does not mean they are the same disease, that they can or should be treated in the same manner or even that a person having ordinary skill in the art would understand them to be related (other than the fact that they involve the brain).

Applicant therefore strongly traverses the Office Action's statement that "mitochondrial encephalopathy lactic acidosis and stroke-like episodes... [is] disclosed as treated by the prior art." Office Action at page 4. Fukumi nowhere teaches or suggests treating MELAS, but only treating *presenium* encephalopathy such as senile dementia and Alzheimer's disease. As is generally known in the art, senile dementia and Alzheimer's disease are in no way related to MELAS.

Similarly, Fukumi's teachings regarding treatment of myoclonus syndrome is irrelevant to the treatment of MELAS, because these two disorders are entirely different

diseases. See, for example, the attached abstract of "Mitochondrial Myopathy, Encephalopathy, Lactic Acidosis, and Strokelike Episodes: A Distinctive Clinical Syndrome" to Pavlakis et al., Annals of Neurology, Vol. 16, Issue 4, pp. 481-488 (1984). Both MELAS and myoclonus syndrome are mitochondrial diseases; however, as admitted by the Office Action, "Fukumi et al do not explicitly purport to treat mitochondrial diseases." Therefore, Fukumi's teaching regarding one particular disease cannot be viewed as teaching the treatment of an entirely different disease.

Accordingly, independent claim 1 would not have been obvious over the applied reference, for at least the reasons discussed above. Dependent claims 2-9 therefore also would not have been obvious for at least the reason that independent claim 1 would not have been obvious.

Reconsideration and withdrawal of the rejection are respectfully requested.

III. Conclusion

In view of the foregoing, it is respectfully submitted that this application is in condition for allowance. Favorable reconsideration and prompt allowance of the application are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact the undersigned at the telephone number set forth below.

Respectfully submitted,



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Enclosure:

Abstract of Pavlakis et al. "Mitochondrial Myopathy, Encephalopathy, Lactic Acidosis, and Strokelike Episodes: A Distinctive Clinical Syndrome."

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☐ 1: [Ann Neurol](#). 1984 Oct;16(4):481-8.

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Mitochondrial myopathy, encephalopathy, lactic acidosis, and strokelike episodes: a distinctive clinical syndrome.

Pavlakakis SG, Phillips PC, DiMauro S, De Vivo DC, Rowland LP.

We report on two patients who have a mitochondrial myopathy, encephalopathy, lactic acidosis, and recurrent cerebral insults that resemble strokes (MELAS). These two and nine other reported patients share the following features: ragged red fibers evident on muscle biopsy, normal early development, short stature, seizures, and hemiparesis, hemianopia, or cortical blindness. Lactic acidemia is a common finding. We believe that MELAS represents a distinctive syndrome and that it can be differentiated from two other clinical disorders that also are associated with mitochondrial myopathy and cerebral disease: Kearns-Sayre syndrome and the myoclonus epilepsy ragged red fiber syndrome. Existing information suggests that MELAS is transmitted by maternal inheritance. The ragged red fibers suggest an abnormality of the electron transport system, but the precise biochemical disorders in these three clinical syndromes remain to be elucidated.

PMID: 6093682 [PubMed - indexed for MEDLINE]

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[Ann Neurol. 1985]

Myoclonus epilepsy with ragged red fibers and multiple mtDNA deletions.

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